company announcement

Wednesday 27 July 2005

Epitan clinical trials to focus on PMLE

Epitan completes strategic review of development program for EPT1647 (formerly MELANOTAN™)

Melbourne, Australia

Epitan Limited today announced that its clinical trial strategy will now focus on Polymorphous Light Eruption (PMLE) as the principal clinical indication for seeking drug registration from regulatory agencies in Australia and internationally.

The reasons for Epitan's decision to concentrate on PMLE are:

- Positive observations in the European proof of concept study
- PMLE is an acceptable indication for registration of EPT1647
- Significantly lower remaining development costs
- There is currently no cure for PMLE

Iain Kirkwood, Epitan CEO and Managing Director, said: "This strategy provides a clear regulatory pathway for EPT1647 which will allow the drug to be brought to market initially for specialist use for a defined patient population. We have already commenced obtaining ethics committee approval for an Australian PMLE-focused study to begin in the spring. This study will be pivotal to our final Phase III program beginning in 2006."

The Phase II proof of concept study was conducted at hospitals in Germany, Finland and Denmark and involved 18 subjects (12 active, 6 placebos). Principal Investigators observed that the patients studied had experienced a therapeutic benefit from the drug. At one hospital it was noted that two patients who would normally have had severe PMLE reactions on exposure to UV on their faces did not experience such a reaction following EPT1647

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treatment. Some of the observations were not recorded as part of the trial protocol but were reported separately during follow up visits by the Principal Investigators. The release of the final report of the pilot PMLE study has been extended by two months to incorporate supplementary research and is expected in October 2005.

Epitan will continue to work on sunburn for EPT1647 and is evaluating other indications such as actinic keratoses (pre-cancerous skin lesions) to widen the potential applications.

In preparation for Phase III and marketing applications, Epitan has engaged ORION Clinical Services, specialists in clinical development. Epitan has passed ORION's quality assurance audit of its clinical dossiers for EPT1647. ORION has also commenced identifying sites in both Europe and USA for future Phase III PMLE studies.

Dr Chris Baker, Director of Clinical Services, Department of Dermatology at St Vincent's Hospital, Melbourne, said: "Polymorphous Light Eruption (PMLE) is a common sun-induced skin disorder. The rash is intensely itchy and consists of obvious red patches and bumps. It occurs on areas of exposed skin after sun exposure and lasts for several days or longer. It is the cause of great inconvenience and discomfort to the sufferer. Although it can occur in any age group it most commonly affects young adult females. In the mild form it is often inappropriately called a "heat rash" or mistakenly blamed on a reaction to sunscreen. In the more severe form, PMLE causes severe irritation and may cause the sufferer to avoid outdoor activities. PMLE will often occur on a sunny holiday, when it is particularly inconvenient, due to the increased intensity of sunlight and outdoor activity.

"Current treatments include the use of oral steroids, UV therapy to desensitize the skin or the so called "antimalarial" drugs. Sunscreens are generally disappointing at preventing PMLE because the wavelengths of sunlight that cause PMLE get through most sunscreens. As the occurrence of PMLE is often predictable in an individual patient, a treatment that would reliably prevent a flare of the condition would be extremely useful and would allow affected people to live a normal outdoor life during the sunnier months."

Dr Lesley Rhodes, Senior Lecturer in Dermatology at the University of Manchester (UK), said: "Polymorphous Light Eruption (PMLE) is a distressing skin condition triggered by sunlight. It occurs every spring and summer, and has a considerable impact on quality of life for many people. There is unfortunately no cure, and phototherapy treatment, sometimes used in the springtime to "toughen" the skin to light, is potentially harmful since it damages DNA. Therefore a treatment which is able to protect the skin by increasing the levels of eumelanin, without causing DNA damage, could be a breakthrough in the treatment of this condition."

About Epitan

Epitan Limited (ASX: EPT, ADR: EPTNY, XETRA: UR9) is a Melbourne-based pharmaceutical company with a focus on prescription dermatology products.

Epitan has two primary activities: (1) to complete the remaining clinical development of its leading drug candidate EPT1647, for which Epitan holds exclusive worldwide rights in the field of use for melanogenesis and (2) marketing and selling prescription dermatology products in Australia and New Zealand.

As at July 2005, Epitan has four drugs in its portfolio of dermatology products. Epitan continues to evaluate the in-licensing of additional similar products although its main focus is to complete the development and commercialisation of EPT1647 for the world markets.

About EPT1647

EPT1647 is the new non-proprietary name for Epitan's MELANOTAN™. MELANOTAN™ is Epitan's brand name for [Nle^4, D-Phe^7]-α-MSH. From June 2005, Epitan is using EPT1647 rather than its brand name to avoid any confusion between MELANOTAN™ (or MT-I) and other chemicals such as Melanotan-II (or MT-II) and melatonin.

EPT1647 stimulates the body to make eumelanin, the dark pigment of the skin which is known to have protective effects on the skin from exposure to both UV-A and UV-B radiation. Simply, EPT1647 is a photoprotective agent that acts by increasing the levels of eumelanin in the skin without the need to expose the skin to UV radiation. Therefore, it has the potential to be used as a photoprotective agent for those persons seeking additional protection from UV damage, because their levels of eumelanin do not normally increase when they are exposed to UV radiation or persons who suffer from the clinical symptoms of UV associated skin diseases and disorders, such as Polymorphous Light Eruption (PMLE).

Appendix 1 – PMLE Background

Polymorphous Light Eruption (PMLE) is a skin disorder which is characterized by recurrent, abnormal delayed reactions to sunlight. It is the most common of the idiopathic photodermatoses. With no cure, this represents a significant unmet medical need with many sources estimating that there are 100 million sufferers worldwide. Sometimes known as "sun

poisoning", the cause is unknown but PMLE is a common reaction to sunlight (ultraviolet light) that occurs in "light-sensitive" individuals. It is the second most common sun-related skin problem after sunburn as seen by doctors.

Symptoms and Causes

Common symptoms of PMLE include non-scarring, itchy, red papules, vesicles or plaques on light exposed skin. These symptoms usually occur within two hours following sun exposure. Symptoms may resolve within hours or remain for up to two weeks after sun exposure.

The cause of the disorder is unknown, however is likely to involve or be dependent upon UV radiation and other factors. Lesions most often occur on seasonally covered areas as they begin to be exposed to sunlight, usually during spring. During summer as the skin becomes more exposed to the sun, frequently exposed areas may become hardened to the effects of sunlight, resulting in a decrease of lesions in these areas.[1]

Prevalence

PMLE is most common in temperate climates where there are distinct changes between seasons. It is reported to affect 15% of the UK population, and 21% of people in Sweden[1,2,3] Approximately 10% of the US population and 3-5% of the Australian population also suffer from PMLE.[2,3]

Treatment Options

While there are many treatments available for PMLE, there is no cure. Prophylactic therapy such as avoiding sunlight, wearing protective clothing, and using broad spectrum sunscreens remains a key factor in the care of patients with PMLE. Other preventative treatment options include exposure to UV light (phototherapy) at the beginning of spring for several weeks to prevent flare-ups throughout the summer and oral corticosteroids in conjunction with phototherapy to avoid eruption during therapy. Topical corticosteroids, antihistamines, "antimalarial" medication and beta-carotene are often used once preventative measures have failed.[3]

Current treatment options available for PMLE suffers are not without risks or side effects, however patients are willing to accept these risks in order to prevent their PMLE from occurring or at least lessening the severity of an outbreak.

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